Docket No.: 07641.0003.CNUS02

**PATENT** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Bill E. Cham

Confirmation No. 2329

Application No.: 10/752,095

Group Art Unit: 1623

Filed: January 1, 2004

Examiner: Elli Peselev

Title: Medicinal Compositions and Their

Method of Preparation

## **RESPONSE TO OFFICE ACTION DATE FEBRUARY 12, 2008**

#### **MS** Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sirs:

Amendments to the Specification: there are no amendments to the specification.

Amendments to the Claims begin on page 2 of this correspondence.

Remarks begin on page 7 of this correspondence.

### **AMENDMENT TO THE CLAIMS**

Prior to further examination please amend the claims as follows. The following listing of claims replaces all prior versions/listings of the claims in the present application.

### 1 - 23 (Canceled)

24. (Previously presented) A method of preparing a glycoalkaloid preparation the method comprising the step of removing free sugars that are present in a purified crystalline or semi-crystalline glycoalkaloid preparation as degradation products of the glycoalkaloid(s) in the preparation wherein the glycoalkaloid preparation comprises at least one glycoalkaloid of the general formula I:

wherein:

either one of the dotted lines represents a double bond, and the other a single bond, or both represent single bonds;

A: represents a radical selected from the following radicals of general formulae (II) to (V):

each of R<sup>1</sup> is a radical separately selected from the group consisting of hydrogen, amino, oxo and OR<sup>4</sup>; each of R<sup>2</sup> is a radical separately selected from the group consisting of hydrogen, amino and OR<sup>4</sup>; each of R<sup>3</sup> is a radical separately selected from the group consisting of hydrogen, alkyl and R<sup>4</sup>O-alkylene; each of R<sup>4</sup> is a radical separately selected from the group consisting of hydrogen and carbohydrate "X" is a radical selected from the group consisting of -CH<sub>2</sub>-, -O- and -NH-;

wherein the compound includes at least one  $R^4$  group in which  $R^4$  is a carbohydrate

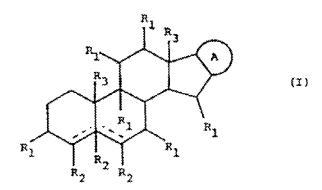
wherein said method produces a glycoalkaloid preparation that is substantially free of sugars resulting the degradation of the glycoalkaloids of said preparation.

- 25. (Previously Presented) The method of claim 24 wherein  $R^4$  is selected from the group consisting of glyceric aldehyde; glycerose; erythrose; threose; ribose; arabinose; xylose; lyxose; altrose; allose; gulose; mannose; glucose; idose; galactose; talose; rhamnose; dihydroxyactone; erythrulose; ribulose; xylulose; psicose; fructose; sorbose; tagatose; and other hexoses  $(C_6H_{12}O_6)$ ; heptoses  $(C_7H_{14}O_7)$ ; octoses  $(C_8H_{16}O_8)$ ; nanoses  $(C_9H_{18}O_9)$ ; decoses  $(C_{10}H_{20}O_{10})$ ; deoxysugars with branched chains; compounds wherein the aldehyde, ketone or hydroxyl groups have been substituted; sugar alcohols; sugar acids; benzimidazoles; the enol salts of the carbohydrates; saccharinic acids; sugar phosphates.
- 26. (Previously Presented) The method of claim 24 wherein the at least one glycoalkaloid is selected from the group consisting of solasonine, solamargine, and tomatine.
- 27. (Previously Presented) The method of claim 24 wherein the free sugar is rhamnose, or a disaccharide, trisaccharide, oligosaccharide or polysaccharide having rhamnose as a sugar moiety thereof.
- 28. (Previously Presented) The method claim 24 wherein the crystalline or semi-crystalline glycoalkaloid preparation is also treated to remove any aglycone therefrom.

- 29. (Previously Presented) The method of claim 24 wherein essentially all the free sugars are removed from the crystalline or semi-crystalline\_glycoalkaloid preparation by washing the extract with an aqueous solvent.
- 30. (Previously Presented) The method of claim 28 wherein the aglycone is removed from the preparation by washing the preparation with an chlorinated hydrocarbon solvent.
- 31. (Previously Presented) The method of claim 30 wherein chlorinated hydrocarbon is chloroform.
- 32. (Previously Presented) The method of claim 24 wherein a time period of at least about 7 days has elapsed between the extraction and removal steps.

Claims 33 - 42(Cancelled)

43. (Previously Presented) A method of preparing a glycoalkaloid preparation the method comprising the step of removing free sugars that are present in a purified crystalline or semi-crystalline glycoalkaloid preparation as degradation products of the glycoalkaloid(s) in the preparation wherein the glycoalkaloid preparation comprises at least one glycoalkaloid of the general formula I:



wherein:

either one of the dotted lines represents a double bond, and the other a single bond, or both represent single bonds;

A: represents a radical selected from the following radicals of general formulae (II) to (V):

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Each of R<sup>1</sup> is a radical separately selected from the group consisting of hydrogen, amino, oxo and OR<sup>4</sup>; each of R<sup>2</sup> is a radical separately selected from the group consisting of hydrogen, amino and OR<sup>4</sup>; each of R<sup>3</sup> is a radical separately selected from the group consisting of hydrogen, alkyl and R<sup>4</sup>O-alkylene; each of R<sup>4</sup> is a radical separately selected from the group consisting of hydrogen and carbohydrate "X" is a radical selected from the group consisting of -CH2-, -O- and -NH-;

wherein the compound includes at least one R<sup>4</sup> group in which R<sup>4</sup> is a carbohydrate;

the method including extracting the at least one glycoalkaloid from a suitable plant material to form crystalline or semi-crystalline extract and removing free sugars that are degradation products of the glycoalkaloid in the crystalline or semi-crystalline\_extract.

44. (Previously Presented) The method of claim 43, wherein  $R^4$  is selected from the group consisting of glyceric aldehyde; glycerose; erythrose; threose; ribose; arabinose; xylose; altrose; allose; gulose; mannose; glucose; idose; galactose; talose; rhamnose; dihydroxyactone; erythrulose; ribulose; xylulose; psicose; fructose; sorbose; tagatose; and other hexoses ( $C_6H_{12}O_6$ ); heptoses ( $C_7H_{14}O_7$ ); octoses ( $C_8H_{16}O_8$ ); nanoses ( $C_9H_{18}O_9$ ); decoses ( $C_{10}H_{20}O_{10}$ ); deoxysugars with branched chains; compounds wherein the aldehyde, ketone or hydroxyl groups have been substituted; sugar alcohols; sugar acids; benzimidazoles; the enol salts of the carbohydrates; saccharinic acids; sugar phosphates.

- 45. (Previously Presented) The method of claim 43, wherein the at least one glycoalkaloid is selected from the group consisting of solasonine, solamargine, and tomatine.
- 46. (Previously Presented) The method of claim 43 wherein the plant material is from a plant of the Solanum genus.
- 47. (Previously Presented) The method of claim 43, wherein the extract is BEC.
- 48. (Previously Presented) The method of claim 43, wherein the free sugar is rhamnose, or a disaccharide, trisaccharide, oligosaccharide or polysaccharide having rhamnose as a sugar moiety thereof.
- 49. (Previously Presented) The method of claim 43 wherein the extract is also treated to remove any aglycone therefrom.
- 50. (Previously Presented) The method of claim 43 wherein essentially all the free sugars are removed from the solid extract by washing the extract with an aqueous solvent.
- 51. (Previously Presented) The method of claim 49 wherein the aglycone is removed from the solid extract by washing the preparation with a chlorinated hydrocarbon solvent.
- 52. (Previously Presented) A method of claim 51 wherein chlorinated hydrocarbon is chloroform.
- 53. (Previously Presented) The method of claim 43 wherein a time period of at least about 7 days has elapsed between the extraction and removal steps.

Claims 54 - 63 (Cancelled)

64. (Previously Presented) The method of claim 24, wherein said step of removing free sugar from a solid glycoalkaloid preparation comprises removing essentially all of the free sugar from the glycoalkaloid preparation.

Claims 65 - 66(Cancelled)